

1. Congress should not assume a role of establishing scientific fact by legislation.

Seven of the findings contained in Section 2 of the Bill are specific conclusions of medical and scientific fact--not conclusions attributed to the Surgeon General of the United States or anyone else, but conclusions of Congress reinforced by its full faith and credit. The overriding question is whether Congress should pronounce such conclusions as its own.

Not only is Congress unqualified to legislate scientific fact, the scientific support for the proposed findings is inadequate.

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"I strongly disagree with the proposed Bills because they misrepresent the present state of scientific knowledge. The Bills are asking Congress to give the Nation a scientific verdict on the causes of complex diseases when much of the evidence is either conflicting or has yet to be presented." (Dr. Booker, p. 4)

"I am appalled at the belief implicit in H.R. 4957, H.R. 5653, . . . that Congress can legislate scientific fact. I urge this august body of well-intentioned legislators to avoid putting itself in such an untenable position." (Prof. Macdonald, pp. 1-2)

"I am opposed to this proposed legislation because I believe its far-reaching 'findings' do not have adequate scientific support." (Dr. Sterling, p. 1)

"I am also very concerned that if all the diseases noted in this Bill are assigned by federal law to smoking, there will be a severe decline in research on and attempted control of many known or suspected environmental causes of disease." (Dr. Furst, p. 8)

For additional excerpts from submitted testimony see Appendix A.

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2. The validity of the findings in the proposed legislation is very much at issue.

Recognized medical and scientific experts have raised serious questions about these findings. A scientific controversy continues about what part, if any, smoking has in causing disease. Congress should not pass this legislation when much more research is needed to answer these questions.

Independent scientists have pointed to research results, apparently ignored by the proponents of the legislation, that are contrary to the findings in H.R. 4957/5653.

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"H.R. 4957 . . . makes such flat, dogmatic statements about a scientific area which I know to be fraught with uncertainties." (Dr. Furst, p. 2)

"That the smoking and health controversy continues is demonstrated by many studies and findings that cannot be explained by a smoking causation hypothesis." (Dr. Farris, p. 2)

"There is by no means unanimity in the scientific community that cigarette smoking can be incontrovertibly labeled as causal." (Dr. Booker, p. 2)

"I respectfully suggest that Congress should encourage good research; I have been advocating this for 30 years. If we had received adequate funding of good research years ago, then many of the questions raised today might have been answered." (Dr. Furst, p. 9)

For additional excerpts from submitted testimony see Appendix B.

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3. After years of research, scientists have never shown that animals develop lung cancer by breathing tobacco smoke.

The failure of scientists to produce lung cancer in laboratory animals exposed to cigarette smoke points out a serious flaw in the claims that smoking causes lung cancer. Many other agents, in the industrial environment especially, have been shown to produce lung cancer in animals, but not cigarette smoke.

Over ten years ago an experiment conducted on beagle dogs by Dr. Auerbach and colleagues received much media attention. These investigators claimed to have succeeded in producing lung cancer in their animals. This research, however, was seriously challenged by independent scientists because of critical defects in the experimental methods used. In particular, the dogs were exposed to smoke via holes cut in their tracheas. This in no way mimics the human smoking experience. Further, the experimental data were not made available for an independent panel to evaluate the claims that the dogs developed lung cancer. This experiment has been generally discredited by many scientists including those opposed to smoking. Further, the claimed Auerbach results have never been replicated in any subsequent work. Replication is always important in scientific experimentation, particularly when the original findings have been questioned.

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"No inhalation studies have shown that tobacco smoke inhalation causes lung cancer." (Dr. Buhler, pp. 6-7)

"A massive experiment to demonstrate that cigarette smoking can cause lung cancer in animals has proved negative." (Dr. Sommers, p. 8)

"Over a period of years we have published a series of papers describing our technique of instilling carcinogens in the lungs of mice, the sensitivity of various strains of mice to carcinogens, and the response of the animals to different hydrocarbons. Yes, development of all histological types of lung cancer is common in animals treated with various carcinogens. It is even possible to rate experimentally the potency of carcinogens as inducers of lung cancer." (Dr. Furst, p. 5)

"Because the Auerbach experiment occasionally resurfaces as virtually the only example of a positive inhalational study result, I feel compelled to repeat some of the criticisms of that study that I voiced in 1972. . . . I consider their conclusions to be unfounded." (Dr. Furst, p. 3)

For additional excerpts from submitted testimony see Appendix C.

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4. Whether cigarette smoking is the cause of lung cancer is sharply disputed by scientists.

Cigarette smoking is not necessary for lung cancer development, because as recent studies have shown there has been a dramatic increase in lung cancer rates in non-smokers. Indeed, the agents causing lung cancer in non-smokers could also be causing lung cancer in smokers. Further, the vast majority of heavy smokers do not develop lung cancer. In fact, more than 90 percent of heavy smokers do not develop the disease.

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"Cigarette smoking is not a necessary factor in human lung cancer, which existed for centuries in radium miners before cigarettes were invented." (Dr. Sommers, p. 2)

"The Comprehensive Smoking Prevention Act of 1982 . . . misuses the scientific definition of 'cause' as that term relates to disease." (Dr. H. Fisher, p. 1)

"And cigarette smoking is neither necessary nor sufficient in the development of human lung cancer, and by the biological definition is not the cause." (Dr. Sommers, p. 3)

"This study challenged the dogma that smoking is the major cause of lung cancer. Using data from a number of broad studies, including The American Cancer Society Study Population, Enstrom showed that there has been a dramatic rise in lung cancer mortality rate among persons who have never smoked." (Dr. H. Fisher, p. 4)

"The fact is that the vast majority of smokers, more than 90% of even heavy smokers, do not develop lung cancer." (Dr. Sommers, p. 3)

"Those who claim smoking causes cancer rely upon the reported statistical association and ignore the inconsistencies of the smoking causation theory in the scientific literature. For example, to date, no one has ever been able to produce lung cancer in laboratory animals through exposure to fresh, whole cigarette smoke. Moreover, the vast majority of smokers never develop lung cancer and there are serious inconsistencies in the epidemiological evidence and dose-response relationships." (Dr. Schrauzer, p.2)

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5. Statistics can never prove that smoking causes disease.

The scientific findings in the Bill are based primarily upon the reports of the Surgeon General. The conclusions in these reports rely mainly on statistical analyses of studies of groups of people--or epidemiological (population) studies. Conclusions about disease causation can never be validly drawn from these studies. In addition, the population studies of smoking and health have serious limitations and defects which make their scientific value highly questionable. (1, 2, 3)

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1. "The widely-held belief that smoking 'causes' lung cancer stems mainly from associations encountered in a wide variety of epidemiologic studies on human populations. Accordingly, it is important to discuss some of the limitations inherent in the use of epidemiologic research studies to access the purported smoking-lung cancer relationship." (Dr. Kupper, p. 2)
2. "As a statistician, I am frequently astonished to see how many people, even many who should know better, treat statistical associations as proof of cause-and-effect relationships. The findings in the proposed Act seem to be a perfect example of this misuse of statistics." (Dr. Sterling, p. 1)
3. "Statistical associations between a factor (such as smoking) and disease . . . cannot prove a causal relationship. Yet, the findings in H.R. 4957 are stated as causal relationships, as though all is proven . . . all is not proven in the smoking and health area." (Dr. Furst, p. 6)

2025047141

#### A. Description of Population Or Epidemiological Studies

Epidemiological studies are investigations of groups of people, not individual persons, designed to learn more about the occurrence of disease and factors that may explain it. Frequently, epidemiological studies, if conducted properly, provide valuable clues for public health workers in their efforts to prevent diseases. Epidemiological studies of infectious diseases (diseases transmitted by a microorganism such as TB or cholera) have proved most useful because laboratory studies have subsequently identified the agents suggested by the epidemiological studies. Non-infectious (chronic) diseases such as cancer, emphysema and heart disease are much more difficult to study using epidemiology; long periods of development and many suspected agents contribute to this difficulty. (4)

An important type of epidemiological study is the ongoing or prospective study of a group of people who are followed over a period of time which may be as long as twenty or more years to see what diseases and deaths occur. At the start of the study, information about the population such as age, gender, race, place of residence, smoking habits, etc., is collected from personal interviews, mailed questionnaires, conferences with relatives and other methods. Another type of epidemiological study is the case-control study, in which the diseases or deaths in a population have already occurred, and historical information about the population is gathered--frequently from interviews with relatives, hospital records or death certificates. In both types of studies a group of people that is not exposed to the suspected factor, for example, the non-smokers, is called the control group; the people with the disease who have been exposed to the suspected factor are called the case group. (5)

The information obtained in either of the above types of epidemiological studies is statistical--mainly counts of disease cases, types of diseases, numbers of men and women of various ages with these diseases, numbers of non-smokers and smokers, etc. They are not laboratory or clinical studies of individual persons. Unlike experimenters using laboratory animals, epidemiologists have no control over the many exposures to which the people studied have been subject and which may be related to their disease experience. The results of epidemiologic studies are usually given as comparisons of disease rates in the control group and in the cases. (6)

These conclusions are statistical conclusions; if the group of smokers has a noticeably higher specific disease rate than the group of non-smokers, it is said that smoking is statistically associated with the specific disease. Other possible suspects, such as exposure to hazardous substances at

work, poor nutrition, or stress, are generally not considered when the investigators conclude that smoking is statistically associated with a specific disease. In brief, epidemiological studies provide general descriptions of disease patterns in population groups and additional information about characteristics or personal habits of the population. (7, 8, 9)

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4. "Such positive associations only indicate a need for other kinds of investigation in order to elucidate the nature of the relationship." (Dr. Hockett, p. 2)

5. "There are two main types of epidemiologic studies: the follow-up study and the case-control study. Such studies have reported an association between smoking and lung cancer. However, both kinds of studies can seriously suffer from the presence of biases." (Dr. Kupper, p. 8)

6. "Epidemiologists generally have no control over what their experimental units (ie., human subjects) may be exposed to over a lifetime. A human being is exposed to a myriad of environmental impingements over a lifetime." (Dr. Kupper, p. 2)

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7. "The increased incidence of disease, ascribed to smoking by epidemiological studies that fail to control adequately for occupation, could well be due to occupational factors." (Dr. Sterling, p. 5)

8. "To date, epidemiological studies of lung cancer have not generally included adequate information about occupational exposures." (Professor Macdonald, p. 13)

9. "Like many other diseases of older age, lung cancer appears to be multifactorial, which means the disease is associated with many things, in addition to smoking. Practically all active researchers now agree on this point. These include: . . . heredity . . . sex and race . . . urban . . . occupation . . . immune competence . . . hormones . . . aging . . . . Currently researchers do not know which, if any, of these or other factors play a role in the causation of lung cancer." (Dr. Sommers, pp. 3-4)

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B. Statistical Associations from Epidemiological Studies Can  
Never Establish Cause and Effect

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associations between a suspected factor and a specific disease do not permit conclusions about a causal relationship. Statistical associations do, however, have a proper role in science. They point to directions for further investigations using different scientific methods. In other words, a statistical association between a factor and a disease indicates that research in the laboratory, in animal experimentation and in clinical studies should be pursued in order to explain the statistical association.

Statistical associations may have nothing whatsoever to do with cause and effect. For example, researchers have found a statistical association between an increased risk of heart disease and sleeping less than five hours a night. No one would seriously claim that there is a causal relationship between heart disease and time spent in bed, but this association points to the need for further study into the reasons why certain people sleep less than the average; stress may well be involved. (10, 11, 12, 13, 14)

It is unscientific and highly misleading to say that cause can be determined from reported statistical associations. Epidemiological studies have their proper use in indicating directions where future research might be profitably undertaken.

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10. "Still more striking is the reported epidemiologic finding that men and women who average seven hours of sleep per night have lower death rates from coronary heart disease than those getting either more or less sleep. Those getting less than five hours had very high death rates and those sleeping ten hours or more per night had higher than average rates." (Dr. Hockett, p. 3)

11. "I have previously pointed out that merely changing the hours in bed of the short term or long term sleepers to seven per night, would be unlikely to change this picture radically." (Dr. Hockett, p. 3)

12. "Positive statistical association, however, --as epidemiologists are aware--does not mean causation. Accordingly, these studies do not support the 'findings' in the proposed amendment." (Dr. Hockett, pp. 1-2)

13. "Most of the claims made against cigarettes are based on statistical coincidence, or statistical association, from which conclusions can be drawn only if all the facts of nature are known, which they are not. This statistical coincidence has given rise to an emotional tide, seized upon by various groups and agencies, and hoped to fill a void in our efforts to achieve a perfect health." (Dr. H.R. Fisher, p. 2)

14. "When analyzing epidemiological findings it is of the utmost importance that the distinction between association and causation should always be borne clearly in mind; those who appreciate the distinction will be careful to observe it in their written statements." (Dr. Burch, p. 1)

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C. The Basic Data from Epidemiological Studies of Smoking and Health are Considered to be of Low Quality and Reliability

The data from which statistical associations between smoking and certain diseases are calculated are recognized to have major scientific defects. All too frequently the data are collected without adequate attention to scientific methods and standards. Consequently, the suspect reliability of these data raises fundamental questions about the validity of conclusions based on the data. The statistical associations derived may indeed be distorted by biases and defects present in the data. (15, 16, 17)

-- Reliability of Data --

(a) The reliability of the data on causes of death has been seriously questioned because this information comes from death certificates. Studies of the accuracy of these certificates have shown high error rates, especially in the case of lung cancer. One of the reasons why death certificates contain errors is because in the vast majority of cases an autopsy is not performed to check the accuracy of the cause of death entered on the certificate by a physician or coroner. The difficulties in determining whether a cancer originated in the lung or originated in another site and traveled to the lung present further problems. (18, 19, 20)

Another area where the reliability of data has been called into question involves smoking habits. Information about amount smoked and duration of the habit are frequently obtained from relatives whose memories may be faulty or who may not answer truthfully questions about smoking. (21)

-- Difficulties in Comparisons of Smokers and Non-Smokers --

(b) In order for conclusions about smoking to have some validity, the smokers and non-smokers studied must be quite similar except for the smoking habit. However, important differences between smokers and non-smokers, aside from the smoking habit, have been recognized by scientists. (22, 23)

Unlike the situation with laboratory animals where the investigator can assign in a random fashion those animals to be exposed to a suspected factor and those who will not be exposed, smokers self-select their habit for many, as yet undetermined, reasons. These reasons may well be related to subsequent disease experience. The epidemiologist has no control over the free choice of persons who choose to smoke. (24, 25)

In addition, smokers have, generally speaking, different personalities from non-smokers which may affect their health status. Those differences may be constitutional or genetic. In other words, inherited characteristics may affect susceptibility to disease independent of smoking. (26, 27)

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15.     ""The basic data for lung cancer incidence thus are of poor quality and uncertain verification." (Dr. Sommers, p. 5)

16.     "I have grave doubts about the statistical associations which have been derived from data which is subject to serious flaws." (Dr. Buhler, p. 3)

17.     "Scientific standards frequently have not been met in epidemiological studies of smoking and health." Dr. Sterling, p. 2)

18.     "Partly because of past and present errors of clinical diagnosis and death certification it is impossible to derive precise quantitative conclusions about the role of cigarette smoking in the pathogenesis of lung cancer." (Dr. Burch, p. 5)

19.     "When death certificate diagnoses are compared to autopsy diagnoses of lung cancer, errors in the death certificates have been found to range from 30 to 60%." (Dr. Sommers, p. 5)

20.     "For example they rely primarily on death certificates for the diagnosis of lung cancer even though studies have shown great unreliability in the death certificate specification of this disease. This is primarily due to confusion between cancers that arise in various parts of the body and spread to the lungs-metastatic cancer-and cancers that start in the lungs-primary cancer." (Dr. H. Fisher, p. 2)

21.     "It is well known that there is considerable inaccuracy associated with the use of exposure information based on questionnaires and interviews with next-of-kin to access habits of deceased relatives with regard to smoking or drinking even though this is often the only source of such information in many epidemiologic studies." (Dr. Kupper, pp. 7-8)

22.     "Actually, there is considerable evidence that smokers are, indeed, a constitutionally different group of people from non-smokers." (Dr. Kupper, p. 5)

23.     "For a valid comparison, the groups must be alike as nearly as possible in all respects except for the item being investigated. In studies of cigarette smoking, matching smokers and non-smokers by sex and age was achieved and it has been assumed that in all other respects the two groups were comparable. This is not true, since in body build, extroversion-introversion, marital history, alcohol use, use of non-prescription medications, police records, military records and other aspects, cigarette smokers are demonstrably different from non-smokers." (Dr. Sommers, p. 4)

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24. "For example, people who smoke have chosen to smoke, and people who do not smoke have chosen not to smoke. Thus, any epidemiologic study comparing smokers and non-smokers suffers from the basic flaw that the individuals have self-selected themselves into these two distinct groups. Thus, any observed differences between two such groups with respect to health outcomes, may not, in fact, be the result of smoking but may instead be due to other more basic factors (e.g., those of a genetic origin) which are necessarily different between the two groups because of the self-selection process itself." (Dr. Kupper, p. 4)

25. "Epidemiologic studies by the nature of the mathematics so far developed deal mainly with random populations. But smokers are self selected, as are non-smokers. Comparisons of selected populations using mathematics valid only for random populations cannot be expected to provide valid answers." (Dr. Sommers, p. 6)

26. "Genetic factors may play a significant role in this excess mortality from lung cancer." (Dr. Rothschild, p. 1)

27. "There can be little doubt that constitutional factors make some contribution to the strong association between cigarette smoking and lung cancer in Western Caucasoid population; it is not yet possible to estimate its extent. In the words of Dr. P. D. Oldham ". . . we still do not know how cigarettes cause lung cancer, nor even, if we are particularly rigorous in our use of scientific logic, whether they do." (Dr. Burch, p. 8)

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In this regard, the generation born between 1890 and 1900 appears to be especially susceptible to lung cancer. It has been suggested that nutrition, the quality of medical care, the influenza epidemics in the earlier part of this century, and other factors may be involved in the unusually high lung cancer rates in this group. (28, 29)

When groups of smokers and non-smokers differ in so many fundamental ways aside from their smoking habits, it is scientifically inadvisable to draw conclusions about what relationship, if any, smoking has to the different disease rates reported in these groups.

-- Other Factors Ignored --

(c) In nearly all major smoking and health studies, inadequate attention has been given to other factors which could be related to the pattern of diseases observed. In particular, occupational exposures to toxic dusts and fumes have received little or no attention from investigators, despite growing recognition that agents in the work place may be related to disease in workers. Further, factors such as nutrition or diet, thought by many to be important for body defenses against diseases, have received little interest. (30, 31, 32)

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28. "I found that (1) the generation born between 1890 and 1900 contributed the largest number of cases; (2) if this trend continues this generation would fade from prominence due to old age; (3) the younger generations do not appear to be replacing this generation in cancer production." (Dr. Langston, pp. 5-6)

29. "With regard to the relationship between genetic differences among individuals and differing levels of disease susceptibility, Janis and Kupper have recently demonstrated by sophisticated statistical methodology the existence of a particular birth cohort (i.e., that group of individuals born around the end of the nineteenth century) which appears to be much more prone to develop lung cancer than do other birth cohorts born either before or after that time. The existence of such high-risk birth cohorts suggests that genetic, prenatal, and neonatal factors can be important determinants of subsequent disease susceptibility." (Dr. Kupper, p. 5)

30. "The tremendous variety of toxic and carcinogenic airborne chemicals produced by industry and released into indoor and outdoor environments, in our homes, in our work places, suggest a set of factors which may be important in lung cancer etiology." (Professor Macdonald, p. 12)

31. "Cancer is an extremely complex, multifactorial disease. Studies indicate that many factors, other than smoking, are statistically associated with cancer. Some of these factors are familial predisposition, exposure to tumor viruses and other biological causing agents, exposure to ionizing radiation and industrial carcinogens, diet, exogenous environmental factors and stress." (Dr. Schrauzer, p. 3)

32. "In short, the increased incidence of disease, ascribed to smoking by epidemiological studies that failed to control adequately for occupation, could well be due to occupational factors." (Dr. Sterling, p. 5)

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D. Major Epidemiological Studies of Smoking and Health  
Are Subject to Severe Criticisms

Before the results obtained from a study of any population can be properly applied to a larger population, the study population must be similar to the larger one--in other words, representative. This is similar to the use of a pre-election poll of a sample of voters; unless the sample represents the general electorate, the results of the poll are valueless.

For example, the American Cancer Society's large study group differed from the American population in many ways. The ACS group's disease experience, educational attainment and geographic distribution were not at all representative of the American population. Also the study of British doctors naturally involved a group unlike the general population in England. In addition, the study of American World War I veterans, the Dorn Study, used a very select group unrepresentative of American males. (33, 34, 35)

Questions about the reliability of the data gathered in several of the major studies are a serious cause for concern.

The information about the ACS population was obtained by volunteers who were aware that one of the goals of this study was to link smoking with disease. Their bias is reflected in the large number of ill people selected who happened to be smokers. It is a grave departure from scientific standards to select a population by means of volunteer contact. (36, 37)

The data obtained from questionnaires sent to the American veterans have been severely criticized because of misclassifications of the smoking habits of a sizable number of the veterans. These misclassification errors could have serious effects on the calculated statistical associations. (38)

Additional biases are present in these studies because the initial enrollees were lost during the subsequent follow-up because of migration, death from other causes and refusal to participate. (39)

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33. "In the first and subsequent Surgeon General's Reports, one of the main sets of supportive data was based on the survey of the American Cancer Society. The inadequacy of this survey was recognized and critically analyzed by many of the foremost statisticians and epidemiologists at the time." (Professor Macdonald, p. 15)

34. "The ACS population was also very different from the general U.S. population with respect to age distribution, educational attainment, racial structure and place of residence. It is clear that these one million men and women were not representative of the U.S. population. Certainly, results of the ACS study cannot legitimately be projected to the general population, yet this has been and is still being done." (Dr. Sterling, p. 2)

35. "Various studies involve particular sub-groups of individuals, which are in no way representative of the general population and which are excellent illustrations of the self-selection syndrome. Examples of such studies are the British male doctors study of Doll and Hill and the studies of 7th Day Adventists." (Dr. Kupper, p. 6)

36. "The data from this large study population were gathered by volunteer workers, and it appears that many of the volunteers had preconceived views on smoking and disease." (Dr. Sterling, p. 2)

37. "In the Cancer Society study, thousands of women volunteers asked of their acquaintances many questions about their personal habits. No one questions the sincerity of the women, but no business would consider basing its sales policy on the results of such a study. The proportion of smokers interviewed bore no resemblance to the proportion of smokers in the population, which demonstrated that the women surveyors went out to find smokers. (Professor Macdonald, pp. 15-16)

38. "A smaller American mortality study, which is still widely quoted, used information obtained from U.S. veterans. I have extensively reanalyzed these data and have found that approximately twenty-five percent of the subjects had been misclassified with respect to smoking habits." (Dr. Sterling, p. 3)

39. "The follow-up study, in addition to the general list of biases already discussed, is subject to a special form of selection bias, namely loss-to-follow-up; in particular, we are referring to individuals who, although initially enrolled in the study at the start of the follow-up study period, are lost during the subsequent follow-up period because of migration, death from other causes, refusal to continue participation, etc." (Dr. Kupper, pp. 8-9)

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## APPENDIX A

"The problem won't be solved by legislating the cause of disease." (Dr. Farris, p. 4)

"It is costly and inappropriate for Congress to busy itself in this area. 'Good health' and 'good behavior' cannot be legislated." (Dr. Sachs, p. 8)

"House bill 5653 should not become law, because its scientific underpinnings are weak and unconvincing." (Dr. Brown, p. 11)

"I am particularly concerned with those parts of the Bills that seem to ask Congress to decide what specifically causes coronary artery disease." (Dr. Booker, p. 3)

"It is hardly in the best interest of either science or government to create the illusion that an attack on a single lifestyle factor will provide the solution for such a complex problem. The proposed legislation creates this illusion and should not be passed into law." (Professor Macdonald, p. 17)

"The 'findings' in the 'Comprehensive Smoking Prevention Act' have not been proven. Moreover, passage of the Act will divert attention from other etiologic leads to the disadvantage of the American Public and the progress of the health sciences." (Dr. Schrauzer, p. 4)

"In short, I regard the Bill as misguided. Mr. Waxman has been misled." (Dr. Burch, p. 9)

"The cause or causes of lung cancer are unknown, and a Congressional finding to the contrary does not alter that situation." (Dr. Buhler, p. 2)

"My own experimental work and review of the scientific literature leads me to the conclusion that cigarette smoking has not been scientifically established to be a cause of atherosclerosis." (Dr. E. Fisher, p. 5)

"Knowledge from medical and scientific research must be interpreted with great care and with an understanding of the great variability of the biological processes. Any action having the force of the Congress of the United States should be based on fact, not conjecture." (Dr. H. Fisher, p. 5)

"The general conclusion would seem to be that in the case of CHD [coronary heart disease], as in the case of lung cancer, proof for the causal influence of smoking is still lacking and is by no means as clear-cut and decisive as is often alleged." (Dr. Eysenck, pp. 10-11)

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"My own research and review of the scientific literature lead me to the conclusion that whether and how smoking might cause heart attacks or cardiopulmonary disease remain open questions." (Dr. Bick, p. 4)

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## APPENDIX B

"It is clear that the smoking and health controversy has not been resolved." (Dr. Farris, p. 4)

"Despite extensive research in animals and observational work in humans, there are many unanswered questions why and how people develop diseases of the cardiovascular system." (Dr. Roberts, pp. 2-3)

"What is certain is that at the moment no final decision can be made about whether or the degree to which cigarette smoking may cause lung cancer or coronary heart disease, how it interacts with other factors (stress, personality), or how we can best protect the health of our citizens in relation to these diseases." (Professor Eysenck, p. 13)

"Here we have a controversy that will be resolved only when each of the categories of research unravels the cascade of events that leads to death or disability." (Dr. Jacobson, p. 2)

"In the light of the critical evidence, I am unable to find any scientific justification for the assertion in the Bill that cigarette smoking causes in the United States over 300,000 unnecessary deaths annually." (Dr. Burch, p. 4)

"The cause or causes of lung cancer are unknown, and a Congressional finding to the contrary does not alter that situation." (Dr. Buhler, p. 2)

"In summary, lung cancer, like many other human cancers, remains a major biological mystery. Epidemiologic studies report a statistical association between cigarette smoking and lung cancer. However, the biomedical experimentation does not support the smoking causation hypothesis." (Dr. Sommers, p. 8)

"It is clear . . . that extensive research data do not support the Congressional finding in H.R. 4957 that a major proportion of the CHD deaths in this country are attributable to smoking." (Dr. Seltzer, p. 10)

"The bill's proposed warning, 'Cigarette smoking is a major cause of Heart Disease,' is not scientifically valid." (Dr. Seltzer, pp. 10-11)

"My studies of emotional stress and clinical experience have led me to question the widely accepted view that high cholesterol, elevated blood pressure and cigarette smoking are the most important factors in the etiology of coronary heart disease." (Dr. Russek, p. 2)

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"The scientific fact of the matter is that no one knows why someone like an industrial worker develops cancer of the lung. Is it because he or she is a smoker or because he or she is an industrial worker?" (Dr. Booker, p. 3)

"Despite what those in the legislative arena might believe, the cause or causes of cancer of the lung (and other organs) remain unknown." (Dr. Booker, p. 2)

"I do not agree that cigarette smoking is the major cause of lung cancer, because I believe very strongly that we do not know the cause or causes of cancer of the lung." (Dr. Langston, pp. 7-8)

"Our only hope for progress in the fight against this dread disease is in innovative medical research, not legislative pronouncements." (Dr. Buhler, p. 3)

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## APPENDIX C

"We just do not know the cause of lung cancer despite a mountainous accumulation of research on the subject. Scientists have not produced the kind of lung cancer associated with smoking-squamous cell carcinoma-in animals exposed to cigarette smoke. Experimental work simply does not support the idea that lung cancer is caused by cigarettes and scientists are looking elsewhere for the cause of cancer, into genetic, environmental, and viral possibilities." (Dr. H. Fisher, p. 5)

"The biomedical experimentation does not support the smoking causation hypothesis." (Dr. Sommers, p. 8)

"Based on my own research and familiarity with the literature, I have concluded that no reliable, reproducible animal studies have shown that the inhalation of cigarette smoke causes lung cancer." (Dr. Furst, pp. 4-5)

"To the best of my knowledge, to date no one has produced the type of lung cancer that is associated with human smoking by exposing experimental animals to inhalation of fresh, whole smoke." (Dr. Hockett, p. 9)

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1. New warning labels are unnecessary.

The American public is highly aware of the claimed health hazards associated with cigarette smoking, most probably as a result of active government and private initiatives in this area since 1965. There is no demonstrated need for further efforts in this regard.

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"All of the studies conducted about consumer awareness of smoking and health issues lead to the conclusion that people are universally aware of the claims that smoking is hazardous to health." (Dr. Blackwell, p. 2)

"The level of public awareness about various smoking and health issues, as demonstrated by the studies and surveys cited in the FTC Staff Report, is extraordinarily high -- much higher than one would expect to result from normal advertising and marketing methods." (Dr. Wind, p. 2)

"In regard to awareness, I strongly disagree with the implication in House Bill #5653 that the American public is still too ignorant of the hazards that have been associated with cigarette smoking. I can think of no health claims in the past 20 years that have received more intensive and pervasive media coverage and governmental attention." (Dr. Brown, p. 8)

For additional excerpts from submitted testimony see Appendix I.

2025047161

2. Arguments for the new warning labels are weak.

The reasons given for the proposed legislation on new warning requirements cannot be supported with persuasive facts. Conclusions that the American public is not aware of the claimed health effects of cigarette smoking are based on misinterpretation of survey results and the erroneous assumption that consumer awareness is synonymous with consumer belief.

2025047162

"The efforts of the FTC Staff to minimize the extent of public awareness on these [smoking and health] issues are based on misinterpretations and misuse of the studies cited in the Report and a fundamental confusion between awareness and belief." (Dr. Wind, p. 2)

"Perhaps most significant is that many of the survey measures assessed beliefs rather than awareness. The distinction between belief and awareness is a critical one given the existing controversy over the health threats presumed to be posed by smoking. Consider the likely situation of a survey participant who recognizes that smoking has been found to be associated with particular health problems but finds the evidence insufficient for demonstrating that smoking causes these health problems. Thus, the person is aware of the claimed link between smoking and some health problems but does not believe that smoking causes the problems." (Dr. Blackwell, p. 5)

For additional excerpts from submitted testimony see Appendix II.

2025047163

3. The proposed warning labels may well have effects not intended.

There is no convincing evidence that proposed legislative changes in the warnings will accomplish the goal set forth. Specific rotating warning labels will not increase public awareness of the claimed health effects of cigarette smoking. In fact there are good grounds to expect the opposite effect.

2025047164

"There is no evidence that specific warnings such as those proposed in H.R. 5653 would result in any increase in public awareness." (Dr. Wind, p. 10)

"Indeed, it is quite possible that the rotational warnings proposed by H.R. 5653 would have an opposite effect of what is intended by the bill's sponsors. The present Surgeon General's warning statement is embedded in the public consciousness, as well or better known than the proposition that people should wear seat belts. If instead appear statements linking smoking to specific health problems, consumers might well conclude that the Surgeon General has changed his opinion and no longer considers smoking to be generally hazardous to health." (Dr. Wind, p. 11)

For additional excerpts from submitted testimony see Appendix III.

2025047165

4. The proposed new warning requirements would not change smoking behavior.

There is essentially no evidence that specific warning labels will lead to behavioral changes, such as more people quitting smoking or fewer people starting to smoke. Also the idea that government should be involved in changing behavior according to its view of what is acceptable has been challenged.

2025047166

"To the extent that the present bill is based on a desire to reduce smoking -- and putting aside the question whether behavior modification is an appropriate goal for government in this country -- the warning statements proposed by Section 4 are simply irrelevant." (Dr. Blackwell, p. 8)

"Since it is basic to human nature to conclude that risks apply to 'the other person,' specific warnings that might be personally relevant to some consumers would by definition be personally irrelevant to most other consumers. For the individual who sees these diseases as unlikely to occur personally, then the proposed new warnings would be less relevant. Such individuals are particularly likely to be young consumers who may be making the decision of whether to smoke or not." (Dr. Blackwell, p. 10)

2025047167

## Appendix I

"It appears to me that, by any standard, the level of awareness about the claimed health hazards of smoking is astonishingly high." (Dr. Blackwell, p. 3)

"It would appear that current studies have underestimated consumers' awareness about the health hazards associated with smoking. . . . But in view of the fact that these same studies consistently report awareness levels in the 80-90 percent range, it is fair to conclude that public awareness of the various claims about smoking and health is as a practical matter universal." (Dr. Blackwell, p. 7)

"With respect to the existing level of public awareness, the FTC Report begins its analysis with the admission that 'most people are generally aware' of the claims about smoking and health. The report cites a 1978 Gallup Opinion poll, which indicates that more than 90 percent of the public believes that smoking is hazardous to health." (Dr. Wind, p. 3)

2025047168

## Appendix II

"Most fundamentally, the [FTC] Report's conclusions, and to a large extent the studies upon which those conclusions are based, reflect a hopeless confusion of the very distinct concepts of awareness versus knowledge and belief." (Dr. Wind, p. 8)

"The [FTC] Staff's conclusion simply does not follow from the data. This fundamental type of error -- confusing consumer awareness with consumer belief -- undermines any recommendations that might be based on a premise that the public is not adequately informed about smoking and health." (Dr. Wind, p. 10)

"Such response variations between questions involving the same disease, but which differ in positing smoking as either the cause of or simply associated with that disease, strongly suggest that many persons classified as 'unaware' in fact are aware of smoking's asserted relationship to various health risks. These persons simply do not believe that smoking causes these health problems." (Dr. Blackwell, p. 6)

"It would be wrong to conclude that consumers are not adequately informed about the claimed health consequences of smoking simply because many consumers continue to smoke." (Dr. Blackwell, p. 7)

2025047169

### Appendix III

"There is neither theoretical nor empirical support for the proposition that the rotational warning system proposed in H.R. 5653 and recommended by the FTC Staff would have any positive impact on the level of public awareness about smoking and health issues." (Dr. Wind, p. 2)

"There are accordingly no data to indicate that a rotational system such as that proposed by the bill would meet the objective of providing consumers with 'sufficient' awareness about the claimed consequences of smoking . . ." (Dr. Blackwell, p. 9)

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